

APPENDIXES

Appendix A. Exact Search Strings

The PubMed® search strategies described below were adapted for use in the Cumulative Index to Nursing & Allied Health Literature database (CINAHL®, search date March 30, 2011) and the Cochrane Database of Systematic Reviews (CDSR, search date March 30, 2011). Results from Searches A and B, described below, were combined to form the full citation set.

PubMed® search strategies:

Search A (February 4, 2011):

1. “medical home” OR “health-care home” OR “advanced primary care” OR “guided care” OR “patient aligned care team” OR “pcmh[tiab]
2. Clinical[tiab] AND trial[tiab]
3. clinical trials[MeSH] OR clinical trial[PT] OR random*[tiab] OR random allocation[MeSH] OR “time points”[tiab]
4. “time series AND interrupt[tiab]
5. pretest[tiab] OR pre-test[tiab] OR posttest[tiab]
6. quasi-experiment*[tiab] OR quasiexperiment*[tiab] OR quasirandom*[tiab] OR quasi-random*[tiab] OR quasi-control*[tiab] OR quasicontrol*[tiab]
7. cluster[tiab] AND trial[tiab]
8. (study[tiab] AND continuing[tiab] OR follow-up[tiab] OR longitudinal[tiab] OR demonstration[tiab] OR intervention[tiab])
9. treatment outcome[MeSH] OR multicenter study[PT] OR comparative study[PT] OR clinical trial OR comparative[tiab] OR comparison[tiab] OR matched[tiab] OR “Evaluation Studies as Topic”[MeSH:noexp] OR “Program Evaluation”[MeSH] OR “Validation Studies as Topic”[MeSH] OR “Multicenter Studies as Topic”[MeSH] OR “Controlled Clinical Trials as Topic”[MeSH:noexp] OR “evaluation studies”[PT]
10. #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9
11. #1 AND #10

Limits:

Language: English

Not: Editorial, Letter, Practice Guideline

Search B (February 16, 2011):

1. "Patient-Centered Care"[MeSH] OR "Delivery of Health Care, Integrated"[MeSH] OR "Patient Care Team"[MeSH:noexp] OR "chronic care model" OR "system redesign" OR "systems redesign" OR "disease management"[mh] OR "patient care management"[MeSH:noexp] OR collaboratives
2. "Primary Health Care"[Mesh:noexp] OR "family practice"[mesh] OR "internal medicine"[Mesh] OR "physicians, family"[mesh] OR geriatrics[Mesh] OR "primary care"[tiab] OR chronic disease[mh] OR "ambulatory Care"[Mesh] OR "Health Services for the Aged"[MeSH] OR "Community networks"[mesh] OR "pediatrics"[Mesh] OR "Child Health Services"[Mesh] OR "Health Care Coalitions"[Mesh] OR (child*[tiab] AND special[tiab] AND health*[tiab]) OR "diabetes mellitus"[Mesh] OR "diabetes mellitus"[tiab] OR "depressive disorder"[Mesh] OR "major depression"[tiab] OR "heart failure"[Mesh] OR "heart failure"[tiab] OR "coronary disease"[Mesh] OR "angina pectoris"[Mesh:noexp] OR hypertension[Mesh] OR hypertension[tiab] OR hyperlipidemias[Mesh] OR hyperlipidemia[tiab]
3. clinical[tiab] AND trial[tiab]) OR clinical trials[MeSH] OR clinical trial[PT] OR random*[tiab] OR random allocation[MeSH] OR "time points"[tiab] OR ("time series" AND interrupt[tiab]) OR pretest[tiab] OR pre-test[tiab] OR post-test[tiab] OR posttest[tiab]
4. quasi-experiment*[tiab] OR quasiexperiment*[tiab] OR quasirandom*[tiab] OR quasi-random*[tiab] OR quasi-control*[tiab] OR quasicontrol*[tiab]
5. (cluster[tiab] AND trial[tiab]) OR (study[tiab] AND continuing[tiab] OR follow-up[tiab] OR longitudinal[tiab] OR demonstration[tiab] OR intervention[tiab])
6. treatment outcome[Mesh] OR multicenter study[pt] OR comparative study[pt] OR clinical trial OR comparative[tiab] OR comparison[tiab] OR matched[tiab] OR "Evaluation Studies as Topic"[Mesh:noexp] OR "Program Evaluation"[Mesh] OR "Validation Studies as Topic"[Mesh] OR "Multicenter Studies as Topic"[Mesh] OR "Controlled Clinical Trials as Topic"[Mesh:noexp] OR "evaluation studies"[pt]
7. #3 OR #4 OR #5 OR #6
8. #1 AND #2 AND #7

Limits:

Language: English

Not: Editorial, Letter, Practice Guideline

Not: Citations from Search A

Appendix B. Data Abstraction Elements (KQs 1–3)

Primary Study Citation (Please list the first author, year, and RefID# for primary article of this study)_____

Study Objective

Does this study specifically state that it is an evaluation of PCMH or the Medical Home?

☐ Yes

☐ No

If no, is there a specific conceptual or organizational model that the study claims it is testing? (check all that apply)

☐ Yes – Accountable Care Organization

☐ Yes – Chronic Care Model

☐ Yes – Clinical Microsystems

☐ Yes – Community-based Primary Care

☐ Yes – Population Health Management

☐ - Yes – Other (please specify): _____

☐ None reported

What is the stated objective of this study (typically the objective from the abstract)?_____

POPULATION

Study Type and Summary

Design Detail (click one)

☐ RCT – Patient-level randomization

☐ RCT – Cluster (e.g. study location/clinic) randomization

☐ Non-randomized Controlled Trial

☐ Prospective Cohort/Observational Study – Defined by patient groups

☐ Prospective Cohort/Observational Study – Study location/clinic

☐ Retrospective Cohort/Observational Study – Defined by patient groups

☐ Retrospective Cohort/Observational Study – Study location/clinic

☐ Interrupted Time series

☐ Intervention and Control Groups, Pre-Post design

☐ Other (specify): _____

Study Sponsor

What type of organization funded the study? (pick the primary funder from acknowledgements)

☐ None reported

☐ Federal (US) – National Institutes of Health

☐ Federal (US) – Agency for Healthcare Research and Quality

☐ Federal (US) – Centers for Medicare and Medicaid Services (CMS)

☐ Federal (US) – Indian Health Services

☐ Federal (US) – Other Health and Human Services Agency

- ☐ Federal (US) – Department of Veterans Affairs
- ☐ Federal (US) – Department of Defense
- ☐ State Government (can include State Medicaid program)
- ☐ Foundation (specify) _____
- ☐ Professional Society (specify) _____
- ☐ Staff or Group Model health maintenance organization (HMO)
- ☐ International government-operated health system (not US)
- ☐ Other (specify) _____

Study Setting – Country

In what country was this study conducted? (check all that apply)

- ☐ United States
- ☐ Other (specify country) _____

Study Setting – Organization Intervention Site

In what type of organization(s) was/were the PCMH intervention done? (check all that apply)

- ☐ Not reported
- ☐ Federal (US) – Department of Veterans Affairs
- ☐ Federal (US) – Department of Defense
- ☐ Federal (US) – Indian Health Service
- ☐ State Government
- ☐ Federally Qualified Health Center
- ☐ Staff or Group Model health maintenance organization (HMO) (specify) _____
- ☐ Other insurance organization (specify, including who owns) _____
- ☐ Integrated delivery system (includes hospital and outpatient services) (specify, including who owns) _____
- ☐ Stand-alone primary care provider (specify, including who owns) _____
- ☐ Government-operated health system outside US (specify, including who owns) _____
- ☐ Other (specify) _____

Comments:

Study Setting – Number of Study Locations

How many intervention locations were included in the study (e.g. how many intervention clinics)? _____

How many control locations were included in the study (e.g. how many control clinics)? _____

Study Population

Overall population category (pick most appropriate level)

- ☐ Adults

___ Children (<= 18 years)

___ Mixed

How many intervention groups (e.g. intervention arms of a clinical trial)? _____

Overall Description (label) for intervention and control arms (e.g. intervention + PCMH implemented; control = usual care)

a. Intervention arm 1:	
b. Intervention arm 2:	
c. Intervention arm 3:	
d. Control arm:	

Patient enrolled (if variable number of patients per outcome, record the largest number for any baseline measure)

a. Total Patient n=	
b. Intervention arm 1 n=	
c. Intervention arm 2 n=	
d. Intervention arm 3 n=	
e. Control arm n=	

Enrollee characteristics (PATIENTS] (only abstract total enrolled if that is available; otherwise, abstract arms separately)

Characteristic:	Total Enrolled (preferred data) N = _____	Arm 1 N = _____	Arm 2 N = _____	Arm 3 N = _____	Control arm N = _____
a. Mean Age (SD)					
b. Sex – Men (n)					
c. Sex – Women (n_					
d. Race – White (n)					
e. Race – African American (n)					
f. Race – Latino (n)					
g. Race – Asian (n)					
h-1. Mean education (years) (SD) OR					
h-2. >High School education (n)					
i. Disease Burden (e.g. risk score) specify:					

j-1. Top 3 Diseases - #1 specify_____					
j-2. Top 3 Diseases - #2 specify_____					
j-3/ Top 3 Diseases - #3 specify_____					

Comments (related to baseline descriptors):

Staff Studied

Are staff outcomes (e.g. staff burn-out, etc.) reported?

___ No

___ Yes

If staff outcomes were included, please indicate the number of staff included in each category (n)

Total n=	
Primary Care Provider (i.e. physician, nurse practitioner, and/or physician assistant) n=	
Nurses (can be any level of licensed nurse not acting as a primary care provider) n=	
Other (specify profession) n=	

Comments:

INTERVENTION – Specific PCMH Components

What specific PCMH components have been included regarding the **Primary Care Team**?

- ☐ no team (defined as ≥ 2 people)
- ☐ team, but no details given
- ☐ team, details given

If team (details given) then check all that apply to the team composition

- ☐ Physician
- ☐ NP/PA
- ☐ Nurse (RN and/or LPN)
- ☐ Clinical Pharmacist
- ☐ Social Worker
- ☐ Psychologist
- ☐ Other (specify) _____

Other team details (check all that apply)

- ☐ Defined roles for team members (paper does not need to describe each role for this item to be checked)
- ☐ Dedicated time for one or more members of the care team to address expanded PCMH activities
- ☐ A team member is designated as the patient's primary contact (if reported, please indicate discipline) specify MD/PA/NP; RN/LPN; Other _____
- ☐ Regular meetings of team or other mechanism to discuss/communicate about patient care
- ☐ Team located in the SAME physical location
- ☐ Team located in DIFFERENT physical locations (e.g. telemedicine, care manager covering multiple practices)
- ☐ Other key aspects (specify): _____

Were specific PCMH components regarding **Enhanced Access** included?

- ☐ Yes
- ☐ No

If yes, check all that apply:

- ☐ There is "enhanced access" but no details reported
- ☐ Telephone visits (a telephonic contact by a health care provider to address clinical issues or telephone disease management)
- ☐ Group visits to address a clinical problem (not one or limited-time classes) or shared medical appointments (group visit that includes medication management)
- ☐ Home visits by a team member
- ☐ Web-based visits or web-based disease management
- ☐ Telephone disease management or home tele-monitoring of disease condition (e.g. home BP monitoring, scales for CHF patients that transmit data to the primary care provider)
- ☐ Two-way e-mail or other mode of electronic messaging to address a clinical issue (e.g. secure messaging)
- ☐ Enhanced telephone system (e.g. system for directing calls to specific care team, adding telephone lines, adding system for returning messages)
- ☐ Expanded office hours
- ☐ Advanced clinic access, open access scheduling, or changes to appointment types or availability
- ☐ 24/7 coverage (e.g. nurse call line or other system where a patient can talk directly to a clinician on demand or in a short period of time)

___ Other (specify) _____

Were specific PCMH components regarding **Coordinated Care** included?

If yes, check all that apply

- ___ There is “coordinated care,” but no details reported
- ___ Integrated mental-health services (mental health professional is co-located or care management services for mental illness)
- ___ Clinical pharmacist provides medication counseling or other direct care patient services (e/t/ chronic disease management)
- ___ Community liaison/enhance system for referral to community resources (system to refer patients to services such as food banks, social services, public health dept.)
- ___ Pre-visit planning (e.g. review appointment schedules or charts to plan how to meet patient needs during visits)
- ___ Coordinates home health services
- ___ Coordination of care transitions (e.g. hospital to outpatient care)
- ___ Test tracking (system to confirm that diagnostic test results have been reviewed and proper follow-up occurred)
- ___ Referral Tracking or f/u by PCMH team (e.g. a system to track referral status and reports from consultants to ensure proper services are received)
- ___ Other (specify) _____

Were specific PCMH components regarding **Comprehensiveness** included?

If yes, check all that apply

- ___ All or most CHRONIC care included
- ___ All or most ACUTE care included
- ___ All or most CHRONIC ILLNESS and/or PREVENTIVE care included
- ___ All or most SPECIALTY care included
- ___ Other (specify services) _____

Were specific PCMH components regarding a **system-based approach to improving quality and safety** included?

If yes, check all that apply

- ___ There is “system-based approach to improving quality and safety,” but no details reported
- ___ Reduced provider/team panel size
- ___ Longer appointment times
- ___ Orientation to the practice (e.g. Medical Home structure/service)
- ___ Evidence-based practice guidelines
- ___ Electronic health records
- ___ Electronic prescribing
- ___ Patient registries or tracking of preventive or chronic illness services (lists of patients, sortable by conditions and/or interventions) and or tracking of preventive or chronic illness services
- ___ Mechanism for identifying high-risk patients (e.g. health risk appraisal, patients with markers of poor disease control, claims data predictive index)
- ___ Point-of-care decision support (e.g. preventive care reminders or guideline based clinical reminders)
- ___ Performance monitoring for quality of care (e.g. performance indicators on process of care,

_____ patient experience, patient outcomes)
_____ Other (specify) _____

Were specific PCMH components regarding a **Sustained Partnership** (with 'Whole Person' focus) included?

If yes, check all that apply

- _____ Sustained partnership, but no details reported
- _____ Designated MD/PA/NP primary care provider
- _____ Care plans used (care plans developed with patients)
- _____ Shared decision making (decision aids introduced or staff training on shared decision making)
- _____ Comprehensive patient health assessments
- _____ Self-management support (e.g. written self-management plan, self-management tolls [written/web], staff training on self-management; specific self-management program)
- _____ Programs for family/caregiver support (e.g. family education or psychoeducation; caregiver training)
- _____ Other (specify) _____

Were specific PCMH components regarding **structural changes to care** included?

If yes, check all that apply

- _____ There were 'structural changes to care,' but no details reported
- _____ New staff
- _____ New services or programs (e.g. group visits, telephone disease management)
- _____ New locations of care
- _____ New organizational entities (e.g. formation of an Accountable Care Organization)
- _____ New organizational affiliations (e.g. new service agreement between a physician practice group and hospital)
- _____ New staff roles (may overlap with team)
- _____ New electronic health record
- _____ New payment model
- _____ Other (specify) _____

Financial Models Introduced as Part of PCMH

What specific models were used as part of the PCMH implementation? (check all that apply)

- _____ No change or nothing reported on financial models
- _____ Bundled payments for most health services (i.e. similar to capitation not specifically related to PCMH support)
- _____ Pay for Performance (i.e. payment based on meeting pre-specified quality targets)
- _____ Enhanced Fee for service (e.g. additional payments for participating in PCMH)
- _____ Accountable Care Organization (or other interorganizational agreement with shared financial risk)
- _____ Revised pharmacy benefits
- _____ Other (specify) _____

Organization Learning Strategies

What mechanisms did the organization use for learning about PCMH and the related components? (check all that apply)

- _____ Learning strategies not reported

- ☐ Designated research/project team assistance
- ☐ Collaborative program planning involving the clinic staff
- ☐ Participated in a formal learning collaborative
- ☐ Community of practice (e.g. group of professionals seeking to improve care supported by phone calls, web site, etc.)
- ☐ Implementation toolkits (i.e. availability of a set of tools to help organizations implement new programs, can include things like instructions on how to develop PCMH structures, conduct rapid cycle improvement, map current care systems)
- ☐ Other (specify) _____

System Change Strategies

What strategies were used to actually implement the changes needed for PCMH? (check all that apply)

- ☐ Strategies not reported
- ☐ Plan-Do-Study-Act Cycles (also sometimes called Plan-Do-Check-Act cycles)
- ☐ Academic detailing
- ☐ Lectures/classes for staff (i.e. didactic education)
- ☐ Flow mapping of care system
- ☐ Total quality management (TQM)/Continuous Quality Improvement (CQI)
- ☐ Audit and feedback to providers, teams, and/or clinics
- ☐ Strengths-Weakness-Opportunities-Threats Analysis
- ☐ External benchmarking at the organizational level (comparing one's organizational quality/performance to that of other organization or an industry standard)
- ☐ Designated clinical champion (facility/practice level)
- ☐ Designated project manager (facility/practice level)
- ☐ Quality Improvement Team
- ☐ Other (specify) _____

COMPARATOR

Please check the type of comparator against which PCMH was compared.

- ☐ Usual care – no changes
- ☐ Changed system other than PCMH (specify basic changes) _____
- ☐ Non-Facilitated PCMH Implementation (as opposed to facilitated PCMH implementation) (specify basic aspects of any “non-facilitation”) _____
- ☐ KQ2/3 = “no comparator necessary”

Please indicate reported aspects of the comparator (e.g. usual care) (check all that apply)

- ☐ Aspects not reported
- ☐ Electronic Health Record
- ☐ Teams (mentioned in any way)
- ☐ Designated primary care providers
- ☐ Clinical practice guidelines
- ☐ Disease management programs for specific diseases
- ☐ Group visits
- ☐ Telephone care
- ☐ Programs for families/caregivers
- ☐ Quality Improvement programs (any mentioned)
- ☐ Quality measurement
- ☐ Access enhancement programs (e.g. open access)

___ Other (specify) _____

Comments:

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Is this study relevant to Key Question 1?

KQ1: In published, primary care-based evaluations of comprehensive PCMH interventions, what are the effects of the PCMH on patient and staff experiences, process of care, clinical outcomes, and economic outcomes?

- a. Are specific PCMH components associated with greater effects on patient and staff experiences, process of care, clinical outcomes, and economic outcomes?
- b. Is implementation of comprehensive PCMH associated with unintended consequences (e.g. decrease in levels of indicated care for non-priority conditions) or other harms?

___ Yes

___ No

If yes, please complete the following Outcomes Table:

Type of Outcome:	Name of Outcome:	How Was Outcome Measure Reported:	Timepoint(s):	Comments
a. Patient/Facility, Staff, N/A				
b. Patient/Facility, Staff, N/A				
c. Patient/Facility, Staff, N/A				
d. Patient/Facility, Staff, N/A				
e. Patient/Facility, Staff, N/A				
f. Patient/Facility, Staff, N/A				
g. Patient/Facility, Staff, N/A				
h. Patient/Facility, Staff, N/A				
i. Patient/Facility, Staff, N/A				
j. Patient/Facility, Staff, N/A				
k. Patient/Facility, Staff, N/A				
l. Patient/Facility, Staff, N/A				

Staff, N/A				
m. Patient/Facility, Staff, N/A				
n. Patient/Facility, Staff, N/A				
o. Patient/Facility, Staff, N/A				
p. Patient/Facility, Staff, N/A				
q. Patient/Facility, Staff, N/A				
r. Patient/Facility, Staff, N/A				
s. Patient/Facility, Staff, N/A				
t. Patient/Facility, Staff, N/A				

Appendix C. Data Abstraction Elements (KQ 4)

Distiller Reference ID: _____

Search Source (choose one):

- ☐ enGrant
- ☐ Commonwealth
- ☐ PCPCC
- ☐ RWJ
- ☐ ClinicalTrials.gov
- ☐ CMS
- ☐ NASHP
- ☐ Medline/PubMed
- ☐ Other (specify) _____

ClinicalTrials.gov identifier (or unique grant #): _____

Study Title: _____

Principal Investigator/Contact: _____

End/Completion date (mm/yyyy): _____

Funder (use data provided on ClinicalTrials.gov form): _____

Health Care Delivery Organization (check all that apply):

- ☐ Not Reported
- ☐ Federal (US) – Department of Veterans Affairs
- ☐ Federal (US) – Department of Defense
- ☐ Federal (US) – Indian Health Service
- ☐ State government
- ☐ Federal Qualified Health Center
- ☐ Staff or Group Model health maintenance organization (HMO) (specify): _____
- ☐ Other insurance organization (specify, including who owns): _____
- ☐ Integrated delivery system (includes hospital and outpatient services) (specify, including who owns): _____
- ☐ Stand-alone primary care provider (specify, including who owns): _____
- ☐ Government-operated health system outside US (specify, including who owns): _____
- ☐ Other (specify): _____

Geographic Location(s):

- ☐ Single State (specify): _____
- ☐ Multi-state

Study Size (enter n or NR for each):

Data Element	Total
Patients:	
Clinics:	
Providers:	

Study Design:

- ☐ RCT – Patient-level randomization
- ☐ RCT – Cluster (e.g. study location/clinic) randomization
- ☐ Non-randomized controlled trial
- ☐ Prospective cohort/observational study – defined by patient groups
- ☐ Prospective cohort/observational study – study location/clinic
- ☐ Retrospective cohort/observational study – defined by patient groups
- ☐ Retrospective cohort/observational study – study location/clinic
- ☐ Interrupted time series
- ☐ Intervention and control groups, Pre-Post design
- ☐ Other longitudinal comparative study (specify): _____

Detailed PCMH components reported (answer yes/no to each):

Team-based care:	Yes/No/NR
Enhanced access to care:	Yes/No/NR
Coordinated care:	Yes/No/NR
Comprehensive care:	Yes/No/NR
Systems-based QI:	Yes/No/NR
Sustained partnership/personal physician:	Yes/No/NR
Reorganization of care delivery:	Yes/No/NR

Comparators (check all that apply – use comments field for any further information)

- ☐ Usual care
- ☐ Other QI approaches
- ☐ PCMH levels

Comments:

PCMH Financial/Reimbursement Model Reported (check all that apply):

- ☐ No change or nothing reported on financial models
- ☐ Bundled payments for most health services (i.e., similar to capitation not specifically related to PCMH support)
- ☐ PCMH per member (typically per month) payment for PCMH/care management activities
- ☐ Pay for Performance (i.e., payment based on meeting pre-specified quality targets)
- ☐ Enhanced Fee for service (e.g., additional payments for participating in PCMH)
- ☐ Accountable Care Organization (or other inter-organizational agreement with shared financial risk)
- ☐ Revised pharmacy benefits
- ☐ Other (specify): _____

Outcomes assessed (check all that apply):

- ☐ Patient or Staff experiences/satisfaction
- ☐ Process of Care – access
- ☐ Process of Care – quality

- ___ Clinical outcomes
- ___ Economic outcomes

Appendix D. Quality (Risk of Bias) Assessment of Individual Studies (KQ 1)

Was this study randomized?

☐ yes
☐ no

If yes, then the following appear (Randomized questions):

Were the study subjects randomized?

☐ yes
☐ no
☐ unclear

Was the randomization process described?

☐ yes
☐ no
☐ unclear

Was the outcome assessor blinded to study assignment?

☐ yes
☐ no
☐ unclear

Were patients blinded to study intervention?

☐ yes
☐ no
☐ unclear

Were results adjusted for clustering?

☐ yes
☐ no
☐ unclear

Were measures of outcomes based on validated procedures or instruments?

☐ yes
☐ no
☐ unclear

Conducted an intent to treat analysis?

☐ yes
☐ no
☐ unclear

Were all outcomes reported (i.e. was there evidence of selective outcome reporting?)

- ☐ yes
- ☐ no
- ☐ unclear

Were incomplete data adequately addressed (i.e. no systematic differences between groups in withdrawals/loss to follow-up AND no high drop-out or loss to follow-up rate [$>30\%$])?

- ☐ yes
- ☐ no
- ☐ unclear

Was there adequate power (either based on pre-study or post-hoc power calculations [80% power for primary outcome])?

- ☐ yes
- ☐ no
- ☐ unclear

Were systematic differences observed in baseline characteristics and prognostic factors across the groups compared?

- ☐ yes
- ☐ no
- ☐ unclear

Were comparable groups maintained? (includes crossovers, adherence, and contamination. Consider issues of crossover [e.g. from one intervention to another], adherence [major differences in adherence to the interventions being compared], contamination {e.g. some members of control group get intervention}, or other systematic difference in care that was provided.)

- ☐ yes
- ☐ no
- ☐ unclear

Was there absence of potential important conflict-of-interest? (Focus on financial conflicts with for-profit capacities; government or non-profit funding = 'yes')

- ☐ yes
- ☐ no
- ☐ unclear

Overall Study Rating:

Please assign each study an overall quality rating of "Good," "Fair," or "Poor" based on the following definitions:

- A **"Good"** study has the least bias, and results are considered valid. A good study has a clear description of the population, setting, interventions, and comparison groups; uses a valid approach to allocate patients to alternative treatments; has a low dropout

rate; and uses appropriate means to prevent bias, measure outcomes, and analyze and report results.

A **“Fair”** study is susceptible to some bias but probably not enough to invalidate the results. The study may be missing information, making it difficult to assess limitations and potential problems. As the fair-quality category is broad, studies with this rating vary in their strengths and weaknesses. The results of some fair-quality studies are possibly valid, while others are probably valid.

A **“Poor”** rating indicates significant bias that may invalidate the results. These studies have serious errors in design, analysis, or reporting; have large amounts of missing information; or have discrepancies in reporting. The results of a poor-quality study are at least as likely to reflect flaws in the study design as to indicate true differences between the compared interventions.

The Overall Quality Assessment of this RCT is:

- ☐ Good
 - ☐ Fair
 - ☐ Poor
-

If no, then the following appear (Observational questions):

This tool is intended to evaluate the quality of studies examining the outcomes of PCMH interventions. Use this risk of bias tool for the following study designs: non-randomized controlled trials, cohort studies, interrupted time series.

Instructions for use:

1. Items are organized by risk of bias domains (selection, performance, attrition, detection and reporting bias). Rate each question using the response categories listed. Focus on study design and conduct, not quality of reporting.
2. Two questions: basic study design, sample size/power are not used in overall ratings but are collected for descriptive purposes.
3. After answering each item, rate the study overall as “low risk of bias,” “moderate risk of bias,” or “high risk of bias” based on the definitions printed in a later section.

Study Design

Is the study design prospective, retrospective, or mixed? (Prospective design requires that the investigator plans a study before any data are collected. Mixed design includes case-control or cohort studies in which one group is studied prospectively and the other retrospectively.)

- ☐ Prospective
- ☐ Retrospective
- ☐ Mixed
- ☐ Cannot determine

Selection Bias

Inclusion/Exclusion Criteria

Are the inclusion/exclusion criteria clearly stated (does not require the reader to infer)? (Key eligibility criteria are: age, medical conditions for patients, specialty if selected by physician, payment structure/vertical integration if selected by clinic.)

Use ‘partially’ if only some criteria are stated or if some criteria are not clearly stated.

- ☐ yes
- ☐ partially (only some criteria stated or some criteria not stated clearly)
- ☐ no

Did the study apply inclusion/exclusion criteria uniformly to all comparison groups?

- ☐ yes
- ☐ partially (only some criteria stated or some criteria not clearly stated)
- ☐ no
- ☐ N/A (study does not include comparison groups)

Recruitment

Did the strategy for recruiting participants into the study differ across study groups? (Also applies if physicians/clinic recruited.)

- ☐ yes
- ☐ no
- ☐ cannot determine
- ☐ N/A (retrospective study design)

Baseline characteristics similar or appropriate adjusted analysis

Are key characteristics of study participants similar between intervention and control groups? (Patients’ age, race, gender, illness severity)

If not similar, did the analysis appropriately adjust for important differences?

- ☐ yes (similar or appropriate adjusted analysis)
- ☐ partially (only some characteristics described or some characteristics not clearly described; analysis adjust for some)
- ☐ no (important baseline differences; unadjusted analysis)

Comparison Group

Is the selection of the comparison group appropriate? (Patients exposed to usual care or enhanced usual care is appropriate; if comparison group determined at the physician or practice level, the comparison groups should be drawn from the same system.)

- ☐ yes
- ☐ no
- ☐ cannot determine (no description of the derivation of the comparison cohort)

___ N/A (study does not include a comparison cohort – case series, one-arm study)

Performance Bias

Intervention Implementation

Did variation from the study protocol compromise the conclusions of the study? (Similar to a psychologist following a manualized procedure to deliver psychotherapy, the PCMH intervention should be implemented as planned.)

- ___ unclear (no data reported on fidelity to protocol or PCMH components used)
- ___ low fidelity (few components of PCMH implemented)
- ___ medium fidelity (most key components of PCMH implemented)
- ___ high fidelity (all key components of PCMH were implemented)

Did researchers rule out any impact from concurrent interventions? (Such as other quality improvement initiatives, changes in payment structure – e.g. through multivariate analysis, stratification, or subgroup analysis?)

- ___ yes
- ___ partially (only some concurrent interventions eliminated)
- ___ not described

Attrition Bias

Equality of length of follow-up for participants

In cohort studies, is the length of follow-up different between the groups? (Where follow-up was the same for all study patients the answer is ‘yes.’ If different lengths of follow-up were adjusted by statistical techniques, for example, survival analysis, the answer is ‘yes.’ Studies where difference in follow-up are ignored should be answered ‘no.’)

- ___ yes
- ___ no
- ___ cannot determine

Completeness of Follow-up

Was there a high rate of differential or overall attrition? (Attrition is measured in relation to the time between baseline [allocation in some instances] and outcome measurement. Standard for overall attrition is <20% for <1 year f/u and <30% for longer term ≥ 1 year. Standard for differential attrition is $\geq 10\%$ absolute difference.)

- ___ yes
- ___ no
- ___ cannot determine

Attrition affecting participant composition

Did attrition result in a difference in group characteristics between baseline and followup?

- ☐ yes
- ☐ no
- ☐ cannot determine

Any attempt to balance the allocation between the groups? (e.g. through stratification, matching, propensity scores)

- ☐ yes
- ☐ no
- ☐ cannot determine

Intention-to-treat analysis

Is the analysis conducted on an intention-to-treat (ITT) basis. i.e., the intervention allocation status rather than the actual intervention received? (Evaluate whether the analysis takes into account loss to follow-up.)

- ☐ yes
- ☐ no
- ☐ cannot determine
- ☐ N/A (retrospective study)

Detection Bias

Blind outcomes assessment

Were the outcomes assessors blinded to the intervention or exposure status of participants?

- ☐ yes
- ☐ no
- ☐ N/A (not an intervention study)

Are interventions/exposures assessed using valid and reliable measures, implemented consistently across all study participants?

- ☐ yes
- ☐ no
- ☐ cannot determine (measurement approach not reported)

Source of information re: outcomes

Are process of care outcomes (e.g. performance measures, access metrics) assessed using valid and reliable measures and implemented consistently across all study participants?

- ☐ yes
- ☐ no
- ☐ cannot determine (measurement approach not reported)

Are clinical outcomes (e.g. symptoms, change in biophysical indicator of disease state) assessed using valid and reliable measures and implemented consistently across all study participants?

- ☐ yes

- ☐ no
- ☐ cannot determine (measurement approach not reported)

Are economic outcomes (e.g. utilizations, costs) assessed using valid and reliable measures and implemented consistently across all study participants?

- ☐ yes
- ☐ no
- ☐ cannot determine (measurement approach not reported)

Are confounding variables assessed using valid and reliable measures, implemented consistently across all study participants? (Major potential confounders include: age, gender, race, disease severity, overall burden of disease.)

- ☐ yes
- ☐ no
- ☐ cannot determine (measurement approach not reported)

Reporting Bias

Primary Outcomes Assessment

Are findings for all primary outcomes reported?
(Abstractor needs to identify all pre-specified, primary outcomes that should be reported in the study.)

- ☐ yes
- ☐ partially (some outcomes not reported)
- ☐ no
- ☐ primary outcomes not pre-specified

Other risk of bias issues

Are the statistical methods used to assess the primary outcomes appropriate to the data?
(The statistical techniques used must be appropriate to the data and take into account issues such as controlling for small sample size, clustering, rare outcomes, and multiple comparison.)

- ☐ yes
- ☐ partially
- ☐ no
- ☐ cannot determine

Power and sample size

Did the authors report conducting a power analysis or some other basis for determining the adequacy of study group sizes for the primary outcome(s) being abstracted?

- ☐ yes
- ☐ no
- ☐ N/A (primary outcomes statistically significant)

Quality – Observational Studies

Definition of “Low,” “Moderate,” and “High” risk of bias:

A "**Low risk of bias**" study has the least bias, and results are considered valid. A good study has a clear description of the population, setting, interventions, and comparison groups; uses recruitment and eligibility criteria that minimizes selection bias; has a low attrition rate; and uses appropriate means to prevent bias, measure outcomes, and analyze and report results. These studies will meet the majority of items in each domain.

A "**Moderate risk of bias**" study is susceptible to some bias but probably not enough to invalidate the results. The study may be missing information, making it difficult to assess limitations and potential problems. As the fair-quality category is broad, studies with this rating vary in their strengths and weaknesses. The results of some fair-quality studies are possibly valid, while others are probably valid. These studies will meet the majority of items in most but not all domains.

A "**High risk of bias**" rating indicates significant bias that may invalidate the results. These studies have serious errors in design, analysis, or reporting; have large amounts of missing information; or have discrepancies in reporting. The results of a poor-quality study are at least as likely to reflect flaws in the study design as to indicate true differences between the compared interventions.

The Overall Quality Rating of this observational study is:

- ☐ low risk of bias
- ☐ moderate risk of bias
- ☐ high risk of bias

Appendix E. List of Included Studies (KQs 1–3)

The Table below lists all studies included for KQs 1–3, broken down into primary and secondary publications.

Table. Included studies (KQs 1–3)

Primary Publication	Secondary Publications
KQs 1–3	
Boult, 2008 ¹	Boult, 2011 ² Boyd, 2010 ³ Leff, 2009 ⁴ Marsteller, 2010 ⁵ Wolff, 2009 ⁶ Wolff, 2010 ⁷
Boyd, 2007 ⁸	Boyd, 2008 ⁹ Sylvia, 2008 ¹⁰
Domino, 2009 ¹¹	None
Dorr, 2008 ¹²	Dorr, 2006 ¹³
Farmer, 2011 ¹⁴	None
Hebert, 2003 ¹⁵	None
Jaen, 2010 ¹⁶	Crabtree, 2010 ¹⁷ Jaen, 2010 ¹⁸ Miller, 2010 ¹⁹ Nutting, 2009 ²⁰ Nutting, 2010 ²¹ Nutting, 2010 ²² Stewart, 2010 ²³
Martin, 2007 ²⁴	None
Reid, 2009 ²⁵	Coleman, 2010 ²⁶ Reid, 2010 ²⁷
Rubin, 1992 ²⁸	None
Schraeder, 2005 ²⁹	Peikes, 2009 ³⁰
Sommers, 2000 ³¹	None
Steele, 2010 ³²	Gilfillan, 2010 ³³
Taplin, 1998 ³⁴	None
Toseland, 1997 ³⁵	Toseland, 1996 ³⁶
Wise, 2006 ³⁷	None
Zuckerman, 2004 ³⁸	Minkovitz, 2003 ³⁹ Minkovitz, 2007 ⁴⁰
KQs 2–3 only	
Chandler, 1997 ⁴¹	None
Farmer, 2005 ⁴²	None
Farris, 2004 ⁴³	None
Palfrey, 2004 ⁴⁴	Samuels, 2005 ⁴⁵
Peleg, 2008 ⁴⁶	None
Rankin, 2009 ⁴⁷	None
Schifalacqua, 2000 ⁴⁸	None
Treadwell, 2009 ⁴⁹	None
Vedel, 2009 ⁵⁰	None

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2. Boulton C, Reider L, Leff B, et al. The effect of guided care teams on the use of health services: results from a cluster-randomized controlled trial. *Arch Intern Med* 2011;171(5):460-6. PMID: 21403043.
3. Boyd CM, Reider L, Frey K, et al. The effects of guided care on the perceived quality of health care for multi-morbid older persons: 18-month outcomes from a cluster-randomized controlled trial. *J Gen Intern Med* 2010;25(3):235-42. PMID: 20033622.
4. Leff B, Reider L, Frick KD, et al. Guided care and the cost of complex healthcare: a preliminary report. *Am J Manag Care* 2009;15(8):555-9. PMID: 19670959.
5. Marsteller JA, Hsu YJ, Reider L, et al. Physician satisfaction with chronic care processes: a cluster-randomized trial of guided care. *Ann Fam Med* 2010;8(4):308-15. PMID: 20644185.
6. Wolff JL, Rand-Giovannetti E, Palmer S, et al. Caregiving and chronic care: the guided care program for families and friends. *J Gerontol A Biol Sci Med Sci* 2009;64(7):785-91. PMID: 19349586.
7. Wolff JL, Giovannetti ER, Boyd CM, et al. Effects of guided care on family caregivers. *Gerontologist* 2010;50(4):459-70. PMID: 19710354.
8. Boyd CM, Boulton C, Shadmi E, et al. Guided care for multimorbid older adults. *Gerontologist* 2007;47(5):697-704. PMID: 17989412.
9. Boyd CM, Shadmi E, Conwell LJ, et al. A pilot test of the effect of guided care on the quality of primary care experiences for multimorbid older adults. *J Gen Intern Med* 2008;23(5):536-42. PMID: 18266045.
10. Sylvia ML, Griswold M, Dunbar L, et al. Guided care: cost and utilization outcomes in a pilot study. *Dis Manag* 2008;11(1):29-36. PMID: 18279112.
11. Domino ME, Humble C, Lawrence WW, Jr., et al. Enhancing the medical homes model for children with asthma. *Med Care* 2009;47(11):1113-20. PMID: 19786921.
12. Dorr DA, Wilcox AB, Brunker CP, et al. The effect of technology-supported, multidisease care management on the mortality and hospitalization of seniors. *J Am Geriatr Soc* 2008;56(12):2195-202. PMID: 19093919.
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21. Nutting PA, Crabtree BF, Miller WL, et al. Journey to the patient-centered medical home: a qualitative analysis of the experiences of practices in the National Demonstration Project. *Ann Fam Med*

- 2010;8 Suppl 1:S45-56; S92. PMID: 20530394.
22. Nutting PA, Crabtree BF, Stewart EE, et al. Effect of facilitation on practice outcomes in the National Demonstration Project model of the patient-centered medical home. *Ann Fam Med* 2010;8 Suppl 1:S33-44; S92. PMID: 20530393.
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24. Martin AB, Crawford S, Probst JC, et al. Medical homes for children with special health care needs: a program evaluation. *J Health Care Poor Underserved* 2007;18(4):916-30. PMID: 17982215.
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Appendix F. List of Excluded Studies (KQs 1–3)

All studies listed below were reviewed in their full-text version for possible inclusion for KQs 1–3 and were excluded. Following each reference, in *italics*, is the reason for exclusion. Reasons for exclusion signify only the usefulness of the articles for this review and are not intended as criticisms of the articles.

Adam P, Brandenburg DL, Bremer KL, et al. Effects of team care of frequent attenders on patients and physicians. *Fam Syst Health* 2010;28(3):247-57. PMID: 20939629. *Exclude—does not meet PCMH definition*

Adams EK, Bronstein JM, Florence CS. The impact of Medicaid primary care case management on office-based physician supply in Alabama and Georgia. *Inquiry* 2003;40(3):269-82. PMID: 14680259. *Exclude—does not meet PCMH definition*

Affi AA, Morisky DE, Kominski GF, et al. Impact of disease management on health care utilization: evidence from the "Florida: A Healthy State (FAHS)" Medicaid Program. *Prev Med* 2007;44(6):547-53. PMID: 17350086. *Exclude—does not meet PCMH definition*

Ahmed S, Gogovor A, Kosseim M, et al. Advancing the chronic care road map: a contemporary overview. *Healthc Q* 2010;13(3):72-9. PMID: 20523157. *Exclude—not original data*

Aita V, McIlvain H, Backer E, et al. Patient-centered care and communication in primary care practice: what is involved? *Patient Educ Couns* 2005;58(3):296-304. PMID: 16122641. *Exclude—does not meet PCMH definition*

Alkema GE, Shannon GR, Wilber KH. Using interagency collaboration to serve older adults with chronic care needs: the Care Advocate Program. *Fam Community Health* 2003;26(3):221-9. PMID: 12829944. *Exclude—does not meet PCMH definition*

Al-Khaldi YM, Al-Sharif AI, Al-Jamal MN, et al. Difficulties faced when conducting primary health care programs in rural areas. *Saudi Med J* 2002;23(4):384-7. PMID: 11953760. *Exclude—does not meet PCMH definition*

Allen JK, Scott LB. Alternative models in the delivery of primary and secondary prevention programs. *J Cardiovasc Nurs* 2003;18(2):150-156. PMID: 2003092559. *Exclude—does not meet PCMH definition*

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Anfinson TJ, Bona JR. A health services perspective on delivery of psychiatric services in primary care including internal medicine. *Med Clin North Am* 2001;85(3):597-616. PMID: 11349475. *Exclude—does not meet PCMH definition*

Anker-Unnever L, Netting FE. Coordinated care partnership: case management with physician practices. *J Case Manag* 1995;4(1):3-8. PMID: 7795541. *Exclude—does not meet PCMH definition*

Anonymous. Integrated management of the sick child. *Bull World Health Organ* 1995;73(6):735-40. PMID: 8907767. *Exclude—does not meet PCMH definition*

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Anonymous. Medicare demonstration project creeping to the starting line. *Capitation Manag Rep* 2004;11(10):109-11. PMID: 15566118. *Exclude—does not meet PCMH definition*

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Appleton PL, Boll V, Everett JM, et al. Beyond child development centres: care coordination for children with disabilities. *Child Care Health Dev* 1997;23(1):29-40. PMID: 9023029. *Exclude—does not meet PCMH definition*

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Artz N, Whelan C, Feehan S. Caring for the adult with sickle cell disease: results of a multidisciplinary pilot program. *J Natl Med Assoc* 2010;102(11):1009-1016. PMID: 2010886437. *Exclude—population and/or setting is not eligible*

Asch SM, Baker DW, Keesey JW, et al. Does the collaborative model improve care for chronic heart failure? *Med Care* 2005;43(7):667-675. PMID: 2009095549. *Exclude—population and/or setting is not eligible*

Bachmann MO, Reading R, Husbands C, et al. What are children's trusts? Early findings from a national survey. *Child Care Health Dev* 2006;32(2):137-46. PMID: 16441848. *Exclude—does not meet PCMH definition*

Badger LW, Ackerson B, Buttell F, et al. The case for integration of social work psychosocial services into rural primary care practice. *Health Soc Work* 1997;22(1):20-9. PMID: 9021415. *Exclude—does not meet PCMH definition*

Bair-Merritt MH, Crowne SS, Burrell L, et al. Impact of intimate partner violence on children's well-child care and medical home. *Pediatrics* 2008;121(3):e473-80. PMID: 2009882610. *Exclude—does not meet PCMH definition*

Barnes-Boyd C, Fordham Norr K, Nacion KW. Promoting infant health through home visiting by a nurse-managed community worker team. *Public Health Nurs* 2001;18(4):225-35. PMID: 11468062. *Exclude—does not meet PCMH definition*

Barnett S, Niebuhr V, Baldwin C. Principles for developing interdisciplinary school-based primary care centers. *J Sch Health* 1998;68(3):99-105. PMID: 9608450. *Exclude—does not meet PCMH definition*

Bartels SJ, Miles KM, Dums AR. Improving the quality of care for older adults with mental disorders: the outcomes-based treatment planning system of the NH-Dartmouth Psychiatric Research Center. *Policy Brief (Cent Home Care Policy Res)* 2002(9):1-6. PMID: 14997912. *Exclude—does not meet PCMH definition*

Basilakis J, Lovell NH, Redmond SJ, et al. Design of a decision-support architecture for management of remotely monitored patients. *IEEE Trans Inf Technol Biomed* 2010;14(5):1216-26. PMID: 20615815. *Exclude—does not meet PCMH definition*

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application of a generic model of chronic illness care. *Milbank Q* 2007;85(1):37-67. PMID: 17319806. *Exclude—does not meet PCMH definition*

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Beland F, Bergman H, Lebel P, et al. Integrated services for frail elders (SIPA): a trial of a model for Canada. *Can J Aging* 2006;25(1):5-42. PMID: 16770746. *Exclude—does not meet PCMH definition*

Benfari RC. The multiple risk factor intervention trial (MRFIT). III. The model for intervention. *Prev Med* 1981;10(4):426-42. PMID: 7027237. *Exclude—does not meet PCMH definition*

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Appendix G. Characteristics of Included Studies (KQ 1, RCTs)

Table. Characteristics of included studies (KQ1, RCTs)

Study	Country; Organization	Explicitly PCMH?; Intervention Components	Practices (n)	Subjects	Outcomes Reported; Followup Period ^a	Study Quality
Farmer, 2011 ¹	U.S.A. Other insurance: Medicaid managed care plan	Yes 1. Coordinated care 2. Team 3. Sustained partnership 4. Comprehensive 5. Enhanced access 6. Structural changes	Intervention (32) Usual care (0) – crossover design	CSHCN – 100 Practice staff - NR	Patient experiences 6 months	Fair
Jaen, 2010 ²⁻⁹	U.S.A. Stand-alone primary care provider: Physician and hospital/health system owned	Yes 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (18) Usual care (17)	Adults – 1983 Practice staff – NR	Patient experiences Staff experiences Process of care Clinical 26 months	Fair
Boult, 2008 ¹⁰⁻¹⁶	U.S.A. HMO: Kaiser- Permanente Mid- Atlantic States; Integrated delivery system: Johns Hopkins Community Physicians; Stand- alone primary care provider: MedStar Physician Partners (multisite group practice)	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (7 PC care teams; 8 practices) Usual care (7 PC care teams; 8 practices)	Older adults with chronic illness – 904 Practice staff - 49	Patient experiences Staff experiences Economic 26 months	Good

Study	Country; Organization	Explicitly PCMH?; Intervention Components	Practices (n)	Subjects	Outcomes Reported; Followup Period^a	Study Quality
Rubin, 1992 ¹⁷	U.S.A. Other: Parkland Memorial Hospital	No 1. Coordinated care 2. Team 3. Sustained partnership 4. Comprehensive 5. Structural changes	Intervention (1) Usual care (NR)	Older adults at high risk for rehospitalization – 200 Practice staff - NR	Economic 26 months	Fair
Schraeder, 2005 ^{18,19}	U.S.A. Integrated delivery system: Carle Health System in Urbana, IL	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (12) Usual care (0)	Older adults with COPD, CAD, DM, CHF, or Afib – 2657 Practice staff – NR	Process of care Economic 2 years	Fair
Sommers, 2000 ²⁰	U.S.A. Stand-alone primary care provider	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (9) Usual care (9)	Older adults with chronic illness – 543 Practice staff – NR	Clinical Economic 2 years	Good
Toseland, 1997 ^{21,22}	U.S.A. Federal (U.S.) – Department of Veterans Affairs	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (1) Usual care (1)	Older adults with chronic illness – 160 Practice staff - NR	Patient experiences Process of care Clinical Economic 2 years	Good

Study	Country; Organization	Explicitly PCMH? Intervention Components	Practices (n)	Subjects	Outcomes Reported; Followup Period ^a	Study Quality
Zuckerman, 2004 ²³⁻²⁵	U.S.A. Other: multiple separate primary care practices across 14 states	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (15) Usual care (15)	Young children – 3737 Practice staff - NR	Patient experiences Process of care 5.5 years	Fair

^aBased on longest followup period among abstracted outcomes.

Abbreviations: Afib = atrial fibrillation; CAD = coronary artery disease; CHF = congestive heart failure; CSHCN = children with special health care needs; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; HMO = health maintenance organization; KQ = key question; NR = not reported; PC = primary care; PCMH = patient-centered medical home; RCT = randomized controlled trial

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Appendix H. Characteristics of Included Studies (KQ 1, Observational Studies)

Table. Characteristics of included studies (KQ1, observational studies)

Study	Country; Organization	Explicitly PCMH?; Intervention Components	Practices (n)	Subjects	Outcomes Reported; Followup Period ^a	Study Quality
Domino, 2009 ¹	U.S.A. Other: State-wide medical home network	Yes 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (NR) Usual care (NR)	Children with asthma – 207,439 Practice staff – NR	Process of care Economic Monthly estimates based on 4 years of data	Good
Martin, 2007 ²	U.S.A. Stand-alone primary care provider: Family practice	Yes 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (1) Usual care (NR)	CSHCN – 199 Practice staff - NR	Economic 2 years	Fair
Reid, 2009 ³⁻⁵	U.S.A. HMO: Group Health Cooperative of Puget Sound	Yes 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (1) Usual care (19)	Adults – 3353 Practice staff – 82	Patient experiences Staff experiences Process of care Economic 2 years	Fair

Study	Country; Organization	Explicitly PCMH?; Intervention Components	Practices (n)	Subjects	Outcomes Reported; Followup Period^a	Study Quality
Steele, 2010 ^{6,7}	U.S.A. HMO: Geisinger	Yes 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (11) Usual care (75)	Older adults with chronic illness – 15,310 Practice staff – NR	Economic 1 year	Fair
Boyd, 2007 ⁸⁻¹⁰	U.S.A. Integrated delivery system Health plan for military retirees; Other: University affiliated community PC practices	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (1) Usual care (1)	Older adults with chronic illness – 150 Practice staff – 2	Patient experiences Economic 6 months	Fair
Dorr, 2008 ^{11,12}	U.S.A. Integrated delivery system: Intermountain Group Health	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (7) Usual care (6)	Older adults with chronic illness – 3432 Practice staff – NR	Clinical Economic 2 years	Good
Hebert, 2003 ¹³	Canada (Quebec) Non U.S. government: Canadian Healthcare System	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (1 region; # of clinics NR) Usual care (1 region; # of clinics NR)	Older adults with chronic illness – 482 Practice staff - NR	Clinical 2 years	Poor

Study	Country; Organization	Explicitly PCMH? Intervention Components	Practices (n)	Subjects	Outcomes Reported; Followup Period ^a	Study Quality
Taplin, 1998 ¹⁴	U.S.A. HMO: Group Health Cooperative of Puget Sound	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Structural changes	Intervention (1) Usual care (27)	Adults – 398,000 Practice staff - NR	Process of care 2 years	Fair
Wise, 2006 ¹⁵	U.S.A. Other insurance organization: Partnership Health in partnership with University of Michigan's Medical Management Center	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive	Intervention (NR) Usual care (NR)	All ages; high utilizers – 54,479 Practice staff - NR	Process of care Clinical Economic 1 year	Fair

^aBased on longest followup period among abstracted outcomes.

Abbreviations: CSHCN = children with special health care needs; HMO = health maintenance organization; KQ = key question; NR = not reported; PC = primary care; PCMH = patient-centered medical home

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Appendix I. Characteristics of Included Studies (KQs 2–3 only)

Table. Characteristics of included studies (KQs 2–3 only)

Study	Country; Organization	Explicitly PCMH?; Intervention Components	Practices (n)	Subjects
Farmer, 2005 ¹	U.S.A. Other: University-affiliated PC clinics	Yes 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (3) Usual care (n/a)	CSHCN – 51 Practice staff – NR
Palfrey, 2004 ^{2,3}	U.S.A. Other: Pediatric Alliance for Coordinated Care	Yes 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (6) Usual care (n/a)	CSHCN – 150 Practice staff – NR
Rankin, 2009 ⁴	U.S.A. Stand-alone PC provider	Yes 1. Quality included 2. Coordinated care 3. Sustained partnership 4. Comprehensive 5. Enhanced access	Intervention (6) Usual care (n/a)	CSHCN – 47 Practice staff – NR
Treadwell, 2009 ⁵	U.S.A. Stand-alone PC provider: 47 PC practices	Yes 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (47) Usual care (NR)	Children with asthma, DM, or ADHD – Practice Staff - NR
Chandler, 1997 ⁶	U.S.A. Federal (U.S.) – Department of Veterans Affairs; Other: Northwestern Memorial Hospital	No 1. Coordinated care 2. Team 3. Sustained partnership 4. Comprehensive 5. Enhanced access 6. Structural changes	Intervention (2) Usual care (n/a)	Adults – 16,000 Practice staff – 3
Farris, 2004 ⁷	Canada Government-operated Health System outside U.S.; Private delivery, but government funded health care system	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (6) Usual care (n/a)	Adults with chronic illness – 199 Practice staff – NR

Study	Country; Organization	Explicitly PCMH?; Intervention Components	Practices (n)	Subjects
Peleg, 2008 ⁸	Israel Non U.S. Government: Israel – PC clinic	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (1) Usual care (n/a)	Older adults – 4620 Practice staff – NR
Schifalacqua, 2000 ⁹	U.S.A. Integrated delivery system: Aurora Health Care of WI	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (NR) Usual care (n/a)	Older adults at medium to high health risk – NR Practice staff – NR
Vedel, 2009 ¹⁰	Paris, France Non U.S. Government: French Health Care System	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (NR) Usual care (2)	Older adults with chronic illness – 100 Practice staff - NR

Abbreviations: ADHD = attention deficit hyperactivity disorder; CSHCN = children with special health care needs; DM = diabetes mellitus; KQ = key question; n/a = not applicable; NR = not reported; PC = primary care; PCMH = patient-centered medical home; RCT = randomized controlled trial

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Appendix J. Characteristics of Included Studies (KQ 4)

Table. Characteristics of ongoing or planned studies evaluating PCMH

Study Title	Projected End Date	Funding Source	Health Care Delivery Organization	Location	Number of Patients ^a	Number of Clinics	Number of Providers
WellStar Health System/Humana Patient–Centered Medical Home	NR	NR	Insurance organization : Humana	Georgia	720	2	12
Metcare of Florida/Humana Patient–Centered Medical Home	11/2010	NR	Insurance organization : Humana	Florida	NR	9	17
Queen City Physicians/Humana Patient–Centered Medical Home	12/2010	NR	Insurance organization : Humana	Ohio	5200	4	18
TriHealth Physician Practices/Humana Patient–Centered Medical Home	5/2011	NR	Insurance organization : Humana	Ohio	1100	1	8
Using multi–payer payment reform to integrate medical home concepts into primary care practice in Washington State	1/2012	RWJ	NR	Washington	NR	NR	NR
Transforming Primary Care Practice In North Carolina	7/2012	AHRQ	NR	North Carolina	NR	12	NR
National Naval Medical Center Medical Home Program	NR	NR	Federal (U.S.): Department of Defense	Maryland	22,500	1	25
EmblemHealth Medical Home High Value Network Project ^b	1/2010	NR	Insurance organization : EmblemHealth	New York	12,000	33	159
Alabama Health Improvement Initiative–Medical Home Pilot	9/2012	NR	Insurance organization : Blue Cross Blue Shield of Alabama	Alabama	NR	14	70
Maine Patient–Centered Medical Home Pilot	11/2012	NR	MaineCare(Medicaid); Maine Health Management Coalition Maine Quality Forum	Maine	30,000 to 50,000	26	221
Transformed Primary Care–Care By Design	6/2012	AHRQ	Multidisciplinary, University–owned primary care practices	Utah	NR	10	NR
Using health information technology and health information exchange to help	1/2012	RWJ	Multipayer	Ohio	30,000	11	40

Study Title	Projected End Date	Funding Source	Health Care Delivery Organization	Location	Number of Patients^a	Number of Clinics	Number of Providers
physician practices improve patient care in Cincinnati							
Evaluating the Effects of EHRs, P4P and Medical Home Redesign in the Hudson Valley	12/2011	Weill Medical College; NY State Dept of Health; The Commonwealth Fund	Taconic Independent Practice Association	New York (Hudson Valley)	250,000	13	210
The Medical HOME Study ^b	1/2015	NIMH	Community Mental Health Centers	Georgia	300	NR	NR
Transforming Primary Care: Evaluating the Spread of Group Health's Medical Home	6/2012	AHRQ	Group model health maintenance organization (HMO): Group Health	Washington	NR	9 for qualitative outcomes; NR for other outcomes	NR
Understanding the Transformation Experiences of Small Practices with NCQA's Medical Home	7/2012	AHRQ	Multiple primary care clinics across the country	Multistate	NR	300	NR
Evaluating Statewide Transformation of Primary Care to Medical Homes	8/2012	AHRQ	All primary care in the state of Minnesota	Minnesota	2,000,000	180	1500
Evaluating the Role of the Medical Home Model in the Successful Management of Diabetes	1/2012	NIH (NIDDK)	NR	California	NR	NR	NR
UnitedHealth Group PCMH Demonstration Program (Arizona)	4/2012	United Health Insurance	Insurance organization: United Health	Arizona	14,000	7	25
Informing Sound Policy: Linking Medical Home Measures and Child Health Outcomes	9/2013	AHRQ	Indiana patient care network of pediatric practices	Indiana	NR	NR	NR
Primary Care Transformation in a NCQA Certified Patient Centered Medical Home	7/2011	AHRQ	Palo Alto Medical Foundation	California	NR	NR	NR
Multi-Method Evaluation of Physician Group Incentive Programs for PCMH Transformation	12/2011	AHRQ	Insurance organization : BCBS of Michigan's	Michigan	1,700,000	NR	7618
Implementation and Impact	9/2012	VA HSRD	Federal (U.S.):	Multistate	NR	> 200	NR

Study Title	Projected End Date	Funding Source	Health Care Delivery Organization	Location	Number of Patients^a	Number of Clinics	Number of Providers
of VA Patient–Centered Medical Home			Department of Veterans Affairs				
What Makes Medical Homes Work: Lessons for Implementation and Spread	4/2012	The Commonwealth Fund	Group model health maintenance organization (HMO): Geisinger	Pennsylvania	50,000	26	110
Evaluation of The Commonwealth Fund's Safety–Net Medical Home Initiative, Phase 2	10/2013	The Commonwealth Fund	Network of safety–net clinics	Multistate	NR	68	NR
Evaluating a Medical Home Demonstration in Colorado and Ohio	6/2011	The Commonwealth Fund	Collaborative of five of the nation's leading insurers (unnamed)	Multistate	NR	NR	NR
Evaluating Models of Medical Home Payment Within the Pennsylvania Chronic Care Initiative	6/2013	The Commonwealth Fund	NR		NR	NR	NR
Rhode Island Chronic Care Sustainability Initiative	10/2011	NR	Unnamed commercial insurers and stand–alone primary care provider	Rhode Island	46,000	13	66
Blue Cross and Blue Shield Tennessee	NR	NR	Insurance organization: Blue Cross Blue Shield	Tennessee	25,000	31	NR
VA PACT Demonstration Lab Initiative	NR	VA HSR&D	Federal (U.S.): Department of Veterans Affairs	Multistate	NR	NR	NR

^aThe number of patients may mean the number of covered lives potentially eligible, or the number of patients specifically participating in the project.

^bStudy planned as a randomized controlled trial.

Abbreviations: AHRQ = Agency for Healthcare Research and Quality; EHR = electronic health record; HMO = health maintenance organization; HSR&D = Health Services Research & Development Service; NCQA = National Committee for Quality Assurance; NIDDK = National Institute of Diabetes and Digestive and Kidney Diseases; NIH = National Institutes of Health; NIMH = National Institute of Mental Health; NR = not reported; P4P = pay for performance; PACT = Patient Aligned Care Team; PCMH = patient-centered medical home; RWJ = Robert Wood Johnson Foundation; VA = United States Department of Veterans Affairs